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|   |             |                      |                              |                  |
|---|-------------|----------------------|------------------------------|------------------|
| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.          | CONFIRMATION NO. |
| 10/808,248  | 03/24/2004  | Elmer M. Price       | UVMO:024US                   | 4363             |
| 32425 7590 04/10/2007<br>FULBRIGHT & JAWORSKI L.L.P.<br>600 CONGRESS AVE.<br>SUITE 2400<br>AUSTIN, TX 78701 |             |                      | EXAMINER<br>MEAH, MOHAMMAD Y |                  |
|   |             |                      | ART UNIT                     | PAPER NUMBER     |
|   |             |                      | 1652                         |                  |
| SHORTENED STATUTORY PERIOD OF RESPONSE  |             | MAIL DATE            | DELIVERY MODE                |                  |
| 3 MONTHS  |             | 04/10/2007           | PAPER                        |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

|                              |                                      |                                     |  |
|------------------------------|--------------------------------------|-------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/808,248 | <b>Applicant(s)</b><br>PRICE ET AL. |  |
|                              | <b>Examiner</b><br>Mohammad Meah     | <b>Art Unit</b><br>1652             |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 1-19 and 25-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>1/14/05</u> | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

Claims 1-35 are pending.

### ***Election/Restriction***

During preliminary amendment of this application, the applicant, on date 01/08/2007 elected without traverse Group III (claims 20-24), drawn to method of treating a subject having vascular disease comprising use of nitric oxide synthase for examination. Groups I-II and IV-V (Claims 1-20 and 25-35) of election/restriction-office action of date 12/07/2006 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions.

### ***Priority***

Acknowledgement is made of applicant's application priority date of 03/24/2003 based on provisional application 60/457,136.

***Claim Rejections***

***35 U.S.C 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20-24 are rejected under U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor at the time the application was filed, had possession of the claimed invention.

These claims are directed to methods of treating any vascular disease or condition with any fusion protein comprising any nitric oxide synthase with any TAT protein. The specification fails to describe in any fashion the physical and/or chemical properties of the claimed class of nitric oxide synthase TAT fusion protein. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear,

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concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Claims 20-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of treating rat for high blood pressure using fusion protein comprising swine endothelial nitric oxide synthase (eNOS, accession NO: NP\_999460) with HIV TAT of SEQ ID NO: 8, does not reasonably provide enablement for treating any Vascular disease or conditions in any mammal such as human using any fusion protein comprising any nitric oxide synthase with any TAT protein. The claims broadly recite the use of **any** fusion protein comprising any nitric oxide synthase with any TAT protein to treat any vascular disease or condition. The specification fails to describe how any fusion protein comprising any nitric oxide synthase with any TAT protein can treat any vascular disease or condition. The specification fails to describe in any fashion the physical and/or chemical properties of the claimed class of substances as discussed above. As the structure of the claimed substances are not defined in any way, one of ordinary skill in the art would not be able to make and use any such substances without undue experimentation to first find what substances in fact fall within the claimed class. Furthermore, the claimed class of compounds is likely to include many compounds, which one of ordinary skill in the art would be unable to make and use without undue experimentation, even if it was known or expected that the substance be within the scope of the claims. Furthermore, even some specific fusion protein comprising specific nitric oxide synthase with specific TAT protein (such as HIV TAT) can treat only some vascular conditions arise from

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decrease of nitric oxide synthase. Vascular conditions or diseases are caused by a wide variety of conditions which are unrelated to nitric oxide synthase or nitrite oxide production, such that a skilled artisan would not find it reasonable that any vascular condition could be treated by **any** fusion protein comprising any nitric oxide synthase with any TAT protein.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including methods of treating with any vascular disease or condition by using **any** fusion protein comprising any nitric oxide synthase with any TAT protein. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of substances having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue.

### ***CLAIM Rejection - 35 U.S.C 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 20-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Blasko et al. (US 2004/0096881 ). Blasko et al. teach methods of treatment of cardiovascular disease comprising delivering a subject endothelial nitric oxide synthase (eNOS) fused with HIV-TAT polypeptide (YGRKKRRQRRR) ( page 17 paragraph 0180, 0181).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mohammad Meah whose telephone number is 571-272-1261. The examiner can normally be reached on 8:30-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status

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information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mohammad Younus Meah, PhD

Examiner, Art Unit 1652

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